REVIEW

A systematic review of *in vivo* retrograde obturation materials

R. Niederman & J. N. Theodosopoulou
The Forsyth Institute, 140 The Fenway, Boston, MA 02115, USA

Abstract

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Purpose The aim of this study was to answer the question: For patients requiring apicoectomy (apicectomy/root-end resection) and retrograde (root-end) obturation (filling), which retrograde obturation (root-end filling) material(s) is/are the most effective, as determined by reduction in periapical radiolucency and elimination of signs and symptoms?

Materials and methods A MEDLINE and a Cochrane search (two specified searches) were conducted to identify randomised (RCT) and nonrandomised controlled clinical trials (CCT), cohort studies (CS) and case-control studies (CCS), published between 1966 and 2002, October week 4, conducted on humans, and published in English, German and French language, relating to retrograde obturation materials following apicoectomy.

Results The MEDLINE and the Cochrane search identified 324 and 21 published articles, respectively. The Cochrane search identified three additional articles to the MEDLINE-search articles. Fourteen studies met the inclusion criteria: two were RCTs, six were CCTs, none was a CS and six were retrospective CCSs. Nine of the 14 studies compared a new retrograde (root-end)-filling material to amalgam, 4 of the 14 studies compared orthograde root canal fillings to retrograde (root-end) amalgam and the fourteenth study compared variations of a resin composite (Retroplast) when used in combination with the bonding agent Gluma (Bayer AG, Gluma 1 and 2). The two RCTs indicated that glass ionomer cement appeared to be equivalent to amalgam. The six CCTs indicated that orthograde filling with gutta-percha and sealer was more effective than amalgam retrograde (root-end)-filling (one trial). Similarly, retrograde (root-end)-filling with (i) composite and Gluma (Bayer AG, Leverkusen, Germany) as bonding agent (one trial), (ii) reinforced zinc oxide eugenol cement (EBA cement) (Stailine, Staident, Middlesex, England; one trial) and (iii) gold leaf (one trial) appeared to be better than amalgam retrograde (root-end)-filling. Finally, gutta-percha retrograde (root-end)-filling appears to be less effective than amalgam (one trial) and Retroplast with ytterbium trifluoride is better than Retroplast with silver, when they are both used with Gluma as bonding agent (one trial).

Conclusions For the highest level of evidence (RCT) retrograde (root-end)-filling with glass ionomer cement is almost as effective as amalgam. However, there was a significant caveat as there were only two RCTs. At the next highest level of evidence (CCT), and given the additional caveat that there was only one controlled trial for each material, retrograde (root-end) EBA cement, composite with Gluma and gold leaf, as well as orthograde gutta-percha, may be more effective than retrograde (root-end) amalgam filling. In conclusion, these results suggest that additional validating CCTs and RCTs are needed.

Keywords: obturation, retrograde, systematic review.

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Correspondence: Richard Niederman, DMD, MS, Senior Scientist, Director, Center for Evidence-Based Dentistry, 140 The Fenway, Boston, MA 02115, USA (Tel.: +1 617 262 5200 374; e-mail: rniederman@forsyth.org).

Introduction

The purpose of this paper was to determine the effectiveness of retrograde obturation (root-end filling) materials based on available high-level evidence from human

clinical trials. The analysis was limited to levels 1–3 of clinical evidence because these are the levels that are able to demonstrate causality.

Apicoectomy (apicectomy/root-end resection) with retrograde (from the apex to the crown/root-end) obturation is a widely applied procedure in endodontics, when all efforts for the successful completion of orthograde endodontic therapy have failed (Gutmann & Harrison 1999). A number of different techniques and materials are used for this purpose in clinical practice. The use of many of these materials is based on studies *in vitro*. Unfortunately, *in vitro* studies cannot provide conclusive determination of results *in vivo*, and direct extrapolation from *in vitro* results to *in vivo* application is risk-laden. Consequently, it is difficult for the clinician to decide which material tested *in vitro* is most likely to be effective *in vivo.*

Materials and methods

Literature search

One electronic search of MEDLINE January 1966 to October week 4, 2002 (Table 1) and the Cochrane Library search (Table 2) were conducted.

Inclusion criteria – validity

Two independent reviewers examined all the identified abstracts to determine whether they met the following criteria:

1 Study *in vivo*
2 Conducted in humans
3 Related to the question
4 Experimental and control group
5 Quantitative results provided
6 English, German, French languages

Whenever it was not possible to make this determination, the article in full text was examined. Subsequently, all relevant articles were obtained and a determination was made by two reviewers if they met the inclusion criteria.

All articles were classified by evidence level (Table 3) (EBM: http://cebm.jr2.ox.ac.uk/docs/levels.html.) and then assessed for validity (Table 4).

Clinical applicability

The number needed to treat (NNT) was calculated using the method of Guyatt *et al.* (1998). For this study, NNT is defined as the number of teeth that would need to be retrograde (root-end)-filled, after apicoectomy (apicectomy/root-end resection) with the experimental material, in order to have successful healing to one more tooth, when compared with the healing result after the use of the control material. Thus, an NNT > 1 indicates that the experimental material is better than the control. An NNT < 1 indicates that the control material is better than the experimental material. Finally, the closer the value of NNT is to 1, the greater is the clinical benefit/damage of the new material. The confidence intervals (C.I.) were calculated using the following equation:

$$\text{C.I.} = \pm 1.96 \sqrt{\left(\frac{\text{CER}(1-\text{CER})}{\#\text{ of control teeth}}\right) + \left(\frac{\text{EER}(1-\text{EER})}{\#\text{ of experimental teeth}}\right)}$$

(http://www.cebm.utoronto.ca/teach/materials/therapy.htm#here).

Results

The MEDLINE search identified 324 articles whilst the Cochrane search identified 21 articles (Tables 1 and 2). The Cochrane search identified three articles in addition to the MEDLINE-search articles, although two of them were irrelevant to the question and one was an *in vitro* study. From 327 articles identified by the literature searches, the hand examination of the titles, abstracts and articles in full text revealed that 172 were irrelevant, 1 could not be found (Person *et al.* 1974) and 152 appeared to be relevant (Tables 5 and 6). Of the 152 articles, 109 were *in vitro* studies, 1 study was in animals, 10 were non-systematic narrative reviews and the remaining 32 were human studies. Of the human studies, two were randomised controlled clinical trials (RCTs), six were nonrandomised controlled clinical trials (CCTs), none was a cohort study (CS), six were case-control studies (CCSs) and one study was a case-series study. Furthermore, 14 were case reports and 2 were not validated because of language limitations (Table 3).

All the identified articles of evidence levels 1–3 compared the healing event rates after the use of various retrograde (root-end) obturation materials. Thirteen trials examined 10 different materials (amalgam, glass ionomer cement, composite with Gluma, reinforced zinc oxide–eugenol cements (EBA cement and IRM), guttapercha (as orthograde and as retrograde (root-end)-filling material), gold leaf, Retroplast with silver or with ytterbium trifluoride and Gluma (as the bonding agent). Thirteen of the 14 articles compared amalgam as a

Table 1 MEDLINE search strategy (324 articles)

Number	Search history	Results
1	Apicoectomy	1064
2	Apicectomy	87
3	Root-end resection	42
4	Root end resection	60
5	Pulpectomy	861
6	Pulpotomy	917
7	Root canal therapy	10780
8	Root canal filling materials	3355
9	Dental pulp test	672
10	Dental pulp disease	5826
11	Periapical abscess	1218
12	Endodontics	15297
13	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12	20950
14	Drug therapy	1017531
15	Therapeutic use	1902127
16	Random*	286065
17	Compar*	2006869
18	14 or 15 or 16 or 17	3749408
19	(Retrograde) or (retro-filling*) or (retro filling*) or (retrofilling*) or (rootend) or (root-end)	33173
20	(Obturation material*) or (obturation) or (filling*) or (filling material*)	27407
21	13 and 18 and 19 and 20	379
22	Limit 21 to human	324

standard control, whilst one compared variations of the same material.

All articles included used the same outcome measure (presence or absence of clinical symptoms/signs, radiographic evaluation of bone reformation and lamina dura around the apical area of the root of the tooth) with an observation period of 0.5–5 years. All characterised results as 'success', 'failure' or 'uncertain/no improvement', in numbers and/or percentages of teeth treated (Tables 7 and 8). Generally, the study designs of the included studies (evidence levels 1–3) did not differ greatly: a surgical intervention was conducted, the apical 3 mm of the root was resected with an angulation of approximately 45° at the long axis of the root and subsequently the experimental or control retrograde (root-end) obturation material was used for each group. Also, the outcome measures were comparable. For every study, the existence of clinical symptoms/signs and/or the enlargement of bone radiolucency 6 months, 1, 3 or 5 years after the surgery, was defined as 'failure'. No clinical symptoms/signs and no reduction of the periapical radiolucency were defined as 'no improvement or uncertain'. No clinical symptoms/signs and elimination of bone radiolucency with or without complete reformation of lamina dura were defined as 'success'. At this point, it should be mentioned that in

Table 2 Cochrane library search strategy (21 articles)

Search history: (((root next canal next filling*) or endodontic* or apicoectomy or apicectomy or (root next end next resection)) and ((retro next filling) or (root next end next filling) or (retrograde next obturation))).

Table 3 Clinical evidence levels*

Level of evidence	Study type	Number
1A	Randomised controlled trial (RCT)	2
	Systematic review of RCTs	0
1B	Controlled trial (CCT)	6
	Systematic review of CCTs[1]	0
2	Cohort study (CS)	0
	Systematic review of CSs	0
3	Case-control study (CCS)	6
	Systematic review of CCSs	0
4	Case series	1
5	Expert's opinion without explicit critical appraisal	0
	Narrative review	10
NA**	Cross-sectional	0
	Case reports	14
	Animal studies	1
	Laboratory studies[1]	109
Nonvalidated	Because of language limitations	2

*EBM: http://cebm.jr2.ox.ac.uk/docs levels.html

**Not applicable.

Table 4 Validity assessment criteria*

Was the assignment of patients of treatment randomised?
Was the randomisation list concealed?
Was the follow-up of patients sufficiently long and complete?
Were all patients analysed in the groups to which they were randomised?
Were patients and clinicians blinded to the treatment being received?
Aside from the experimental treatment, were the groups treated equally?
Were the groups similar at the start of the trial?

*Evidence-Based Medicine. How to Practice and Teach EBM, 2nd ed., Sackett D *et al.*, Churchill Livingstone, Edinburgh, UK.

some articles, success is considered to be 'complete healing' and 'scar-tissue healing'. The number of the teeth treated varies between the studies from 10 to 388. Thus, except the materials used and the number of teeth, the studies have been conducted in quite a similar way.

Table 5 Analysis of the MEDLINE search results (324)

Type of study	Number
In vivo[1]	32
In vitro[1]	108
In animals	1
Expert's opinion/review	0/10
Irrelevant to the question	172
Not found	1
All studies	324

[1]One, same study is both *in vivo* and *in vitro*.

Table 6 Analysis of the Cochrane search results (21)

Type of study	Number
In vivo	4
In vitro	11
Irrelevant to the question	6
All studies	21

Table 7 Methods and results of the included randomised controlled clinical trials (RCTs) and nonrandomised controlled clinical trials (CCTs)

	Retrograde obturation materials				Results in (%)		
Reference	Control group	Experimental group	N_C/N_E	Outcome measures/duration	Success (C/E)	Failure (C/E)	Uncertain/No improvement (C/E)
Zetterqvist *et al.* (1991) (RCT)	Amalgam	Glass ionomer cement (Chem-Fil II, DeTrey, Switzerland)	52/53	Success: Radiographic bone regeneration and/or reformation of lamina dura. No improvement: No radiographic bone regeneration. Failure: Increased radiolucency and/or clinical symptoms. 1 year	90/89	8/9	2/2
Jesslen *et al.* (1995) (RCT)	Amalgam	Glass ionomer cement (Chem-Fil II, DeTrey, Switzerland)	41/41	The same 1 and 5 years	90/90	7.5/7.5	2.5/2.5
Dalal & Gohil 1983 (CCT)	Amalgam	Glass ionomer cement	15/10	The same 0.5 year	93.6/90	6.6/10	–
Pantschev *et al.* (1994) (CCT)	Amalgam	EBA cement (Stailine, Staident, UK)	52/51	The same 3 years	51.9/56.9	28.9/19.6	19.2/23.5
Waikakul & Punwutikorn (1991) (CCT)	Amalgam	Gold leaf	25/41	The same 0.5–2 years	95.7/89.8	0/2.6	4.3/7.7
Rud *et al.* (1991) (CCT)	Amalgam	Composite + Gluma	388/388	The same 0.5–1 years	62/78	8/7	30/15
Dalal & Gohil (1983) (CCT)	Amalgam	Gutta-percha	15/15	The same 0.5 years	93.6/80	6.6/20	–
Grung *et al.* (1990) (CCT)	Amalgam	Gutta-percha orthograde root canal filling	161/312	The same 1 year	72/96	16/1	12/3
Rud *et al.* (1996) (CCT)	Retroplast with Silver and Gluma	Retroplast with ytterbium trifluoride + Gluma	388/351	The same 1 year	78/82	7.5/6	14.5/12

N_C = Number of controls; N_E = number of experiments.

Table 8 Methods and results of the included retrospective CCSs

Reference	Retrograde obturation materials: Control group	Retrograde obturation materials: Experimental group	N_C/N_E	Outcome measures/duration	Results in (%): Success (C/E)	Failure (C/E)	Uncertain/No improvement (C/E)
Rapp *et al.* (1991)	Amalgam	EBA (Teledyne Getz, Elk Grove Village, IL)	120/81	Success: Radiographic bone regeneration and/or reformation of lamina dura. No improvement: No radiographic bone regeneration. Failure: Increased radiolucency and/or clinical symptoms. 0.5–>2 years	71/65	9/5	20/30
Dorn & Gartner (1990)	Amalgam	Super EBA (Harry J. Bosworth Co., Skokie, IL)	294/65	The same 0.5 year	58.2/75	24.8/5	17/20
Rapp *et al.* (1991)	Amalgam	IRM (L.D. Chaulk, Milford, DE)	120/25	The same 0.5–>2 years	71/68	9/4	20/28
Dorn & Gartner (1990)	Amalgam	IRM (L.D. Chaulk, Milford, DE)	294/129	The same 0.5 year	58.2/74	24.8/9	17/17
Molven *et al.* (1991)	Amalgam	Laterally condensed gutta-percha orthograde filling	111/111	The same 1–8 years	73/96.4	12.6/0.9	14.4/2.7
Malmstrom *et al.* (1982)	Amalgam	Chloropercha and gutta-percha orthograde filling	78/104	The same 0.5–1.5 years	76.9/91.3	10.2/6.7	12.8/1.9
Rud *et al.* (1972)	Amalgam	Gutta-percha orthograde filling	229/733 237/197	The same 1 year The same 2–15 years	73/83 83/91	5/1 9/3	22/16 8/6
Reinhart *et al.* (1995)	Amalgam	Glass ionomer cement	113/21	The same 1 year	95/74	5/26	–

N_C = Number of controls; N_E = number of experiments.

Analysis of the results of the randomised and nonrandomised controlled clinical trials

Randomised controlled clinical trials

The two RCTs (Zetterqvist *et al.* 1991, Jesslen *et al.* 1995) compared glass ionomer cement (Chem-Fil, DeTrey, Switzerland) as a retrograde (root-end) obturation material to amalgam. The NNTs calculated were 46 (C.I. 95% = ±0.12) and 8 (C.I. 95% = ±0.12), respectively, suggesting that glass ionomer is slightly more effective than amalgam (Tables 7 and 9).

Nonrandomised controlled clinical trials

Glass ionomer cement, as a retrograde (root-end)-filling material, was compared to amalgam by a CCT (Dalal & Gohil 1983) as well. The NNT was −6 (C.I. 95% = ±0.39). This study (NNT = −6) suggests that amalgam is more effective than glass ionomer cement (Tables 7 and 9).

EBA cement (Stailine, Staident, UK; experimental group) was compared to amalgam (control group; Pantschev *et al.* 1994) and it appeared to be more effective. The observation period was 3 years postoperatively. The NNT calculated was 13 (C.I. 95% = ±0.16). This indicates that 13 teeth needed to be treated with EBA cement rather than with amalgam for one tooth to have a better outcome (Tables 7 and 9).

Gold leaf (experimental group) was compared to amalgam (control group; Waikakul & Punwutikorn 1991). The NNT was 16 (C.I. 95% = ±0.12), inferring that 16 teeth needed to be retrograde (root-end)-filled with gold leaf in order to have one more successful healing after 1 year, when compared to amalgam (Tables 7 and 9).

Composite bonded to dentine with Gluma (Bayer AG, Leverkusen, Germany) (experimental group) was compared to amalgam retrograde (root-end)-filling (Rud *et al.* 1991). The NNT calculated was 7 (C.I. 95% = ±0.098), indicating that composite with Gluma is better than amalgam (Tables 7 and 9).

Gutta-percha, as a retrograde (root-end)-filling material (experimental group), was compared to amalgam (control group; Dalal & Gohil 1983). The NNT calculated was −9 (C.I. 95% = ±0.35). These results suggest that amalgam provides better healing success rates in endodontic surgery than gutta-percha when they are used as retrograde (root-end)-filling materials (Tables 7 and 9).

Table 9 NNT calculations for RCTs and CCTs*

Author(s)	Retrograde obturation materials		NNT	Confidence Intervals** (C.I. (95%))
	Control group	Experimental group		
Randomised CCTs				
Zetterqvist *et al.* (1991)	Amalgam	Glass ionomer cement	46	±0.12
Jesslen *et al.* (1995)	Amalgam	Glass ionomer cement	+8	±0.12
CCTs				
Dalal & Gohil (1983)	Amalgam	Glass ionomer cement	−6	±0.39
Pantschev *et al.* (1994)	Amalgam	EBA cement	13	±0.16
Waikakul & Punwutikorn (1991)	Amalgam	Gold leaf	16	±0.12
Rud *et al.* (1991)	Amalgam	Composite + Gluma	7	±0.1
Dalal & Gohil (1983)	Amalgam	Gutta-percha	−9	±0.35
Grung *et al.* (1990)	Amalgam	Gutta-percha orthograde root canal filling	4	±0.1
Rud *et al.* (1996)	Retroplast with silver + Gluma	Retroplast with ytterbium trifluoride + Gluma	25	±0.057

*NNT: The number of teeth (apices) that need to be filled with the experimental material in order to have another success (or failure: when NNT < 0).

In addition, gutta-percha, as an orthograde filling material (experimental group), was compared to amalgam retrograde (root-end)-filling (control group) (Grung *et al.* 1990). The NNT calculated was 4 (C.I. 95% = ±0.073), indicating that proper root canal filling gives better healing results than amalgam retrograde (root-end)-filling (Tables 7 and 9).

Retroplast containing ytterbium trifluoride (special resin composite) and Gluma (dentine-bonding agent; Bayer AG; experimental group) was compared to Retroplast containing silver (special resin composite) and Gluma (dentin-bonding agent; Bayer AG; control group; Rud *et al.* 1996). The NNT calculated was 25 (C.I. 95% = ±0.057), indicating that 25 teeth needed to be retrograde (root-end)-filled with Retroplast containing ytterbium trifluoride with Gluma, in order to have one more successful healing after 1 year (Tables 7 and 9).

Analysis of the results of the case-control studies

EBA (reinforced zinc-oxide–eugenol cement; (Teledyne Getz, Elk Grove Village, IL, USA; Rapp *et al.* 1991) and Super-EBA (Harry J. Bosworth Co., Skokie, IL, USA; Dorn & Gartner 1990) were compared to amalgam. The NNTs calculated were −25 (C.I. 95% = ±0.132) and 5 (C.I. 95% = ±0.12), respectively. These results suggest substantial differences. The first study suggests that amalgam is better than EBA, whilst the second study suggests that S-EBA is superior to amalgam (Tables 8 and 10).

IRM (reinforced zinc-oxide–eugenol cement; L.D. Chaulk, Milford, DE, USA) was compared with amalgam (Dorn *et al.* 1990, Rapp *et al.* 1991). The NNTs calculated were −100 (C.I. 95% = ±0.20) and 5 (C.I. 95% = ±0.094), respectively, also suggesting substantial differences. The first study indicates that IRM is almost as effective as amalgam, whilst the second study indicates that IRM is significantly more effective than amalgam (Tables 8 and 10).

Orthograde filling of the root canal with laterally condensed gutta-percha and sealer before the root-end resection was compared to amalgam retrograde (root-end)-filling (Molven *et al.* 1991). The NNT was 4 (C.I. 95% = ±0.088), suggesting that proper orthograde root canal fillings with gutta-percha and sealer might be more effective than amalgam retrograde (root-end)-fillings (Tables 8 and 10).

Orthograde filling of the root canal with chloropercha and gutta-percha and sealer before the root-end resection was compared to retrograde (root-end) amalgam filling (Malmström *et al.* 1982). The NNT was 7 (C.I. 95% = ±0.1), suggesting that chloropercha and gutta-percha root canal fillings, when used as orthograde root canal fillings, might give better healing-event rates than amalgam retrograde (root-end)-fillings (Tables 8 and 10).

Orthograde filling of the root canal with gutta-percha was compared to amalgam retrofilling (Rud *et al.* 1972). The NNT, calculated 1 year after surgery, was 8 (C.I. 95% = ±0.06), and at 2–15 years after surgery, it was 13 (C.I. 95% = ±0.05), suggesting that proper orthograde root canal fillings with gutta-percha and sealer might be more effective than amalgam retrograde (root-end)-fillings (Tables 8 and 10).

Glass ionomer cement was compared to amalgam (Reinhart *et al.* 1995). The NNT was 5, indicating that the success rates for amalgam after 1 year were higher than those observed after use of glass ionomer cement as retrograde (root-end)-filling materials. This difference, as reported by the authors, was significant ($P < 0.001$).

However, in all CCS studies that compared orthograde gutta-percha fillings and retrograde (root-end) glass

Table 10 NNT* calculations for the included retrospective CCSs

Reference	Retrograde obturation materials		NNT	Confidence Intervals (C.I. (95%))
	Control group	Experimental group		
Rapp *et al.* (1991)	Amalgam	EBA	−25	±0.132
Dorn & Gartner (1990)	Amalgam	Super EBA	5	±0.12
Rapp *et al.* (1991)	Amalgam	IRM	−100	±0.20
Dorn & Gartner (1990)	Amalgam	IRM	5	±0.094
Molven *et al.* (1991)	Amalgam	Laterally condensed gutta-percha orthograde filling	4[1]	±0.088
Malmstrom *et al.* (1982)	Amalgam	Chloro-percha and gutta-percha orthograde filling	7[1]	±0.107
Rud *et al.* (1972)	Amalgam	Gutta-percha orthograde filling	8[1] (1 year)	±0.06
			13[1] (2–15 years)	±0.05
Reinhart *et al.* (1995)	Amalgam	Glass ionomer cement	5[2]	–

*NNT: The number of teeth (apices) that need to be filled with the experimental material in order to have another one success (or failure, when NNT < 0).

[1]Experimental group. Control group, at baseline.

[2]NNT $= [1/(\%\text{ success of experimental} - \%\text{ success of control})] \times 100$.

ionomer cement fillings with retrograde (root-end) amalgam fillings, the experimental and control groups were not identical in all aspects at baseline. It could not be identified whether the distribution of the cases between the experimental and control groups at baseline was random or not.

Discussion

Many retrograde (root-end) obturation materials alone and/or in combination with various sealers, bonding agents and/or varnishes have been tested *in vitro* to demonstrate their sealing ability and effectiveness. However, very few have been tested *in vivo* in humans. Relevant as *in vitro* studies are in testing new products, more valuable tests are *in vivo* human clinical trials. Thus, the aim of this study was to identify, if possible, the best material for retrograde (root-end)-fillings that can demonstrate effectiveness, based on the current best evidence.

Amalgam is a biocompatible and easy-in-operation material that has been used as a retrograde (root-end)-filling material since 1884 (Farrar 1884 in Gutmann & Harrison 1999). Thus, new materials are usually compared to amalgam. In the search results, a great number of materials (over 30 different groups of materials in various combinations) that have been tested as retrograde (root-end)-filling materials were converged, nevertheless, in *in vitro* studies. At the case reports/case series (14/1) mineral trioxide aggregate (MTA), cold gutta-percha and thermoplasticised injectable gutta-percha, Biocem (Biocem AG Zürich, Diavet AG Bäch), a retrograde (root-end)-filling material with guided tissue regeneration, amalgam, Cavit, aluminium oxide ceramic pins and resin with a dentine-bonding agent have been used as retrograde (root-end)-filling materials (Table 11). In the 109 *in vitro* studies, more than 30 different groups of materials were tested alone and/or in combination with cements, sealers, sealants, bonding agents and/or varnishes. Interestingly, only 10 materials were tested *in vivo* in humans and were compared to a control.

The available *in vivo* human trials suggest that (Tables 9 and 10):

1 Glass ionomer is almost equivalent to amalgam (two studies (RCT); 105 and 82 teeth, respectively).

2 Glass ionomer might, as well, be worse than amalgam (two studies (CCT); 25 and 189 teeth, respectively).

3 EBA cement (one study (CCT); 103 teeth) may be better, or significantly better (one study (CCS); 359 teeth), but also, might be worse (one study (CCS); 201 teeth) than amalgam.

4 IRM (two studies (CCS); 423 and 145 teeth, respectively) is either significantly better (first study) or almost equivalent (second study) to amalgam.

5 Gold leaf is better than amalgam (one study (CCT); 66 teeth).

6 Amalgam is better than retrograde (root-end) gutta-percha filling (one study (CCT); 30 teeth), but worse than orthograde gutta-percha filling (one study (CCT); 473 teeth and three studies (CCS); 222, 182 and 1000 teeth, respectively).

Most interesting, perhaps, is the fact that materials such as MTA, although promising, based on *in vitro* trials and uncontrolled case reports, have been recently widely used as retrograde (root-end) obturation materials. However, no controlled human clinical trials were identified by this study (Table 11).

In summary, whilst there is a vast literature of *in vitro* trials, and a vast literature of uncontrolled *in vivo* human

Table 11 Excluded from this systematic review studies

Reference	Evidence level	Reason for exclusion	Control material	Experimental/presented material
Rud *et al.* (1989)	1	Published as Rud *et al.* (1991)	–	Resin and a dentin bonding agent
Rud *et al.* (1997)	4	Case series	–	Dentin- bonded resin composite
Johnson (1999)	5	Narrative review	–	–
Mounce *et al.* (1995)	5	Narrative review	–	–
Jou & Pertl (1997)	5	Narrative review	–	–
Guldener (1994)	5	Narrative review	–	–
Tyas (1992)	5	Narrative review	–	Glass ionomers
Friedman (1991)	5	Narrative review	–	–
Palaniak (1984)	5	Narrative review	–	–
Merlini *et al.* (1989)	5	Narrative review	–	–
vanRiesen *et al.* (1990)	5	Narrative review	–	Glass ionomer cement
D'Haeseleire *et al.* (1989)	5	Narrative review	–	Ag-points, gutta-percha, amalgam
Joffe (2002)	NA	Case report	–	MTA
Koh (2000)	NA	Case report	–	MTA
Sauveur *et al.* (2000)	NA	Case report	–	Gutta-percha
Ilgenstein *et al.* (1995a)	NA	Case report	–	Biocem
Ilgenstein *et al.* (1995b)	NA	Case report	–	Biocem
Duggins *et al.* (1994)	NA	Case report	–	A retrograde (root-end) -filling material + guided tissue regeneration
Keller (1990)	NA	Case report	–	Aluminium oxide ceramic pins
Marlin (1990)	NA	Case report	–	Thermoplasticised injectable gutta-percha
Hohenfeldt *et al.* (1985)	NA	Case report	–	Amalgam
Alexander (1983)	NA	Case report	–	–
Goldberg *et al.* (1990)	NA	Case report	–	Thermoplasticised gutta-percha (Ultrafill)
Rud & Munksgaard (1989)	NA	Case report	–	Resin and a dentin bonding agent
Passi *et al.* (1982)	NA	Case report	–	–
Modla & Szabo (1981)	NA	Case report	–	Cavit
Nagase (1999)	Not validated	Japanese language	–	–
Grgurevic (1983)	Not validated	Serbo-Croatian language	–	Amalgam
Persson *et al.* (1974)	–	Not found	–	–

clinical trials, very few controlled human clinical trials are available. On the other hand, their results do not always lead to similar conclusions. The few trials need validation by additional controlled trials.

Conclusions

Glass ionomer cement is as effective as amalgam, considering the outcomes of only two RCTs. Considering the outcomes of the CCTs, retrograde (root-end) EBA cement, composite with Gluma and gold leaf, as well as orthograde gutta-percha fillings, may be more effective than amalgam retrograde fillings. However, because of the limited number of *in vivo* RCTs for these materials (one each), additional studies would augment additional validation.

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